

Other means of inducing hypothermia which do not require external pumping including the use of the catheter has been proposed. For example, U.S. Pat. No. 5,486,208 to Ginsburg, describes a catheter that is inserted into a blood vessel and a portion of the catheter heated or cooled, transferring heat to the patient's blood and thereby affecting the overall body temperature of the patient. The U.S. Pat. No. 7,004,961 ~~Appl. No. 20040138728~~ to Wong, describes inserting an elongated device into a lateral ventricle or other space of a brain; inflating a balloon disposed at an end of the device with a fluid; and controlling the an internal temperature of the brain by circulating the fluid within the said balloon. The U.S. Pat. No. 6,929,656 to Lennox describes an apparatus including a brain-cooling probe and a control console that cools the brain by withdrawing a small amount of cerebrospinal fluid from a ventricle into a cooling chamber located ex-vivo, and after cooling the cerebrospinal fluid it is reintroduced back into the ventricle. The U.S. Pat. 7,144,418 to Lennox discloses a method and system for selective cerebral hypothermia. The U.S. Pat. No. 6,217,552 to Barbut describes a device with two elongated catheters, a pump, a refrigeration system and a manometer. The proximal ends of the catheters are connected to the pump and refrigeration system, while the distal ends are adapted for insertion into the subarachnoid space. The cerebrospinal fluid is aspirated from the first catheter to the pump, cooled to below body temperature, and returned to the second catheter. The device is used for treatment of patients with spinal trauma undergoing aortic surgery. The U.S. Pat. 6,660,026 to Larnard et al disclose a multi-tipped cooling probe for the brain. The U.S. Pat. No. 6,592,612 ~~Appl. 20040143312~~ described a catheter for heat exchange apparatus which reside inside the catheter body for selectively altering the temperature of fluid that flows through the catheter shaft. One clear advantage of such devices and methods is that they may avoid the problems associated with external pumping of blood, however they

CROSS-REFERENCE TO RELATED APPLICATION

5,486,208	Jan., 1996	Ginsburg	607/106
6,558,412	May, 2003	Dobak, III	607/105
6,197,045	Mar., 2001	Carson	607/104
6,620,187	Sep., 2003	Carson et al.	607/104
6,547,811	Apr., 2003	Becker et al.	607/105
6,581,400	Jun., 2003	Augustine et al.	62/259.3
6,126,680	Oct., 2000	Wass	607/96
5,916,242	Jun., 1999	Schwatz	607/113
6,217,552	Apr., 2001	Barbut et al	607/113
6,660,026	Dec., 2003	Larnard et al.	607/104
6,622,725	Sep., 2003	Fisher et al.	128/204.21
6,929,656	Aug., 2005	Lennox	607/105
<u>7,144,418*</u>	<u>Dec., 2006</u>	<u>Lennox</u>	<u>607/105</u>
<u>7,004,961*</u>	<u>Feb., 2006</u>	<u>Wong et al</u>	<u>607/105</u>
<u>6,592,612</u>	<u>Jul., 2003</u>	<u>Samson et al.</u>	<u>607/105</u>

US PATENT APPLICATON

20040143312	Jul., 2004	Samson et al.	607/105
20040138728	Jul., 2004	Wong et al.	607/105

* cited by examiner.



UNCLEAN COPY

Claims:

21. (New) A method for hypothermia and rewarming of the cerebrospinal fluid in the brain comprising the steps of:

- (a) providing a heat-exchange ventricular catheter;
- (b) simultaneously with (a) providing a drainage ventricular catheter;
- (c) internally implanting the distal ends of the heat exchange and drainage catheters into the cerebral ventricle through a burr hole or twist drill;

whereby the catheters are placed within the ventricle using ventricular catheter introducers anchored into a slit opening and perforated hole to the distal ends of the catheters respectively, the distal end of the catheter placed above the level of foramen Monro within the ventricle;

- (d) connecting the proximal end of the heat-exchange catheter ~~connected~~ to an infusion system;
- (e) providing an infusion system containing sterile physiologic solution being at a temperature other than that of the cerebrospinal fluid, wherein a sterile physiologic solution flows in a fluid line into the heat-exchange catheter, the sterile physiologic solution of known chemical constituents, and prepared to preserve cell metabolic energy stores;
- (f) providing an infusion pump programmed to deliver the sterile physiologic solution at a predetermined rate;
- (g) infusing the sterile physiologic solution directly ~~infused~~ into the cerebral ventricles;

- (h) mixing the sterile physiologic solution with cerebrospinal fluid and altering the temperature of the fluid bathing the regulatory centers in the brain, whereby the sterile physiologic solution mixes with the chemistry of the cerebrospinal fluid bathing the regulatory centers in order to maintain neuronal viability;
 - (i) draining excess cerebrospinal fluid through the drainage catheter to maintain the desired intracranial pressure;
 - (j) providing pulsatile movement of cerebrospinal fluid to cause heat exchange spreading throughout the brain and spinal cord;
 - (k) altering the temperature of cerebrospinal fluid and blood bathing wider brain areas including those involved in regulation of temperature, pain, and emotional stress and further thereby altering central afferents to the neurons in both the preoptic anterior hypothalamus and posterior hypothalamus;
 - (l) resetting the body temperature based on the temperature of the cerebrospinal fluid;
 - (m) modulating physical pain by promoting antinociceptive response;
 - (n) reducing psychological pain by reducing stimulation of periaqueductal gray area of the brain stem;
 - (o) reducing intracranial pressure by physical contraction of the cerebrospinal fluid volume in response to hypothermia;
 - (p) reducing intracranial pressure and spinal subdural pressure gradients by drainage of excess cerebrospinal fluid;
 - (q) improving neuronal cell energy stores by decreasing the cerebral metabolic rate;
- and

- (r) reducing overall brain temperature by reducing metabolic heat production.
22. (New) The method of claim 1, wherein both the heat-exchange and drainage catheter are made of ~~silieon~~ silicone elastomer tubing.
23. (New) The method of claim 2, wherein the said ~~silieon~~ silicone elastomer tubing is impregnated with barium sulfate to provide radiopacity.
24. (New) The method of claim 3, wherein the said ~~silieon~~ silicone elastomer tubing of the heat exchange and drainage catheters are physically joined together on a firm polypropylene plate to provide rigidity, insulation and resistance to kinking and forming a single catheter with double lumen or double barrel at the proximal, mid and distal portions.
25. (New) The method of claim 4, wherein the said ~~silieon~~ silicone elastomer tubing is graphite-impregnated at points 5, 10, 15 cm from the proximal tip to enable the surgeon to gauge the depth of the penetration of the catheter into the lateral ventricle.
26. (New) The method of claim 5, wherein the said the distal portion of the heat exchange catheter has four slit openings at 90 degrees near the distal end, designed to provide protection from retrograde flow and occlusion of the catheter, and the distal portion of the drainage catheter has perforated holes.
27. (New) The method of claim 6, wherein the heat exchange and drainage catheter joined together forming a double barrel catheter is introduced into the ventricle using a ventricular introducer held between the first and third fingers of one hand like a pair of Chinese chopsticks with the tips inserted into the slit openings and perforated holes and released into the ventricle by a swift action.

28. (New) The method of claim 7, wherein the said proximal portion of the catheters has two right angle clips that are designed to angulate each catheter so that the proximal portion of the heat exchange catheter is turned away from the proximal portion of the drainage catheter.
29. (New) The method of claim 8, wherein the proximal end of the heat exchange catheter is connected to an infusion pump with regulated flow rate of cooling fluid at a set temperature, and the proximal end of the drainage catheter is connected to a cerebrospinal fluid flow control valve attached to an implanted ventriculo-peritoneal or ventriculo-atrial shunting system.
30. (New) The method of claim 9, wherein the depth of hypothermia is determined by the flow rate and temperature of the physiologic solution.
31. (New) The method of claim 10, wherein the depth of hypothermia is monitored by a system of neurointensive care monitoring devices providing the physiologic and biochemical indices of brain function, said neurointensive care devices operatively responsive to set threshold changes in depth of hypothermia and changes in cerebral autoregulation and cerebral vasoreactivity.
32. (New) A method for hypothermia and rewarming of the cerebrospinal fluid in the brain comprising the steps of:
- (a) providing a heat-exchange ventricular catheter forming a blind loop at the distal end;
 - (b) simultaneously with (a) providing an ~~efferent~~ afferent arm for inflow of heat exchange fluid;

- (c) simultaneously with (b) providing an afferent arm for outflow of heat exchange fluid;
- (d) providing a proximal end with an inlet and outlet to the catheter lumen through which the heat exchange fluid flows continuously;
- (e) internally implanting the heat exchange loop catheter into the cerebral ventricle through a burr hole or twist drill;

whereby the catheters are placed within the ventricle using ventricular catheter introducers anchored into a slit opening and perforated hole to the distal ends of the catheters respectively, the distal end of the catheter placed above the level of foramen Monro within the ventricle;

- (f) connecting the proximal end of the heat-exchange catheter ~~connected~~ to an infusion system;
- (g) providing an infusion system containing heat exchange fluid being at a temperature other than that of the cerebrospinal fluid, wherein a heat exchange fluid flows in a fluid line into the heat-exchange loop catheter distal end;
- (h) providing pulsatile movement of cerebrospinal fluid to cause heat exchange spreading throughout the brain and spinal cord;
- (i) altering the temperature of cerebrospinal fluid and blood bathing wider brain areas including those involved in regulation of temperature, pain, and emotional stress and further thereby altering central afferents to the neurons in both the preoptic anterior hypothalamus and posterior hypothalamus;
- (j) resetting the body temperature based on the temperature of the cerebrospinal fluid;

- (k) modulating physical pain by promoting anti-nociceptive response;
- (l) reducing psychological pain by reducing stimulation of periaqueductal gray area of the brain stem;
- (m) reducing intracranial pressure by physical contraction of the cerebrospinal fluid volume in response to hypothermia;
- (n) improving neuronal cell energy stores by decreasing the cerebral metabolic rate; and
- (o) reducing overall brain temperature by reducing metabolic heat production.

33. (New) The method of claim 12, wherein the said blind loop catheter is made of ~~silicon~~ silicone elastomer tubing.

34. (New) The method of claim 13, wherein the said ~~silicon~~ silicone elastomer tubing is impregnated with barium sulfate to provide radiopacity.

35. (New) The method of claim 14, wherein the said ~~silicon~~ silicone elastomer tubing of the catheter has afferent and efferent arms that are physically joined together on a firm polypropylene plate to provide rigidity, insulation and resistance to kinking placed in the middle to form a single continuous catheter with proximal, mid and distal portions ending in a blind loop.

36. (New) The method of claim 15, wherein the said polypropylene plate had perforated holes through which the tip of the ventricular catheter introducer could be inserted.

37. (New) The method of claim 16, wherein the said ~~silicon~~ silicone elastomer tubing is graphite-impregnated at points 5, 10, 15 cm from the proximal tip to enable the

surgeon to gauge the depth of the penetration of the catheter into the lateral ventricle.

38. (New) The method of claim 17, wherein the blind loop catheter is introduced into the ventricle using a ventricular introducer held between the first and third fingers of one hand like a pair of Chinese chopsticks with the tips inserted into the perforated holes in the middle plate and released into the ventricle by a swift action.
39. (New) The method of claim 18, wherein the said proximal portion of the catheters has two right angle clips that are designed to angulate each catheter so that the proximal portion of the afferent arm of the catheter is turned away from the proximal portion of the efferent arm of the catheter.
40. (New) The method of claim 19, wherein the proximal end of the afferent arm of the blind loop catheter is connected to an infusion pump with regulated flow rate of cooling fluid at a set temperature, and the proximal end of the catheter is connected to a cerebrospinal fluid flow control valve attached to an implanted ventriculo-peritoneal or ventriculo-atrial shunting system.